



RESEARCH PROTECTIONS UPDATE



News and Comments on the Protection of Human Subjects in Navy and Marine Corps Research

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DIRECTOR'S CORNER

By CDR F. Jay Haran

As the newly appointed Director of the Department of Navy Human Research Protection Program (DON HRPP), I am excited to bring a diverse range of experiences to this program. My background includes serving as a Primary Investigator, a member and Vice-Chair of multiple Institutional Review Boards (IRBs), and a Human Research Protection Official. These roles have provided me with a deep understanding of the human research protection processes and the challenges commands face in maintaining compliance.

I join you from the Department of the Navy Office of Culture and Force Resilience, Chief of Naval Personnel (OPNAV N17), where I worked for RDML Mietus, the architect of the “Get Real, Get Better (GRGB)” mindset. This approach emphasizes the importance of self-assessment, self-correction, and a culture of continuous learning. Over the past few weeks, I have been actively engaging with colleagues and mentors, listening to their insights, and familiarizing myself with the internal programmatic procedures.

One of my primary goals in this role is to strike a balance between efficiency, flexibility, and rigorous oversight. To that end, my initial focus will be on reviewing and updating the current SECNAVINST 3900.39E CH-1. I aim to maximize the flexibilities offered to commands while ensuring robust oversight and compliance. Your feedback on this instruction is invaluable, and we are seeking your input.

I am proud to be a part of the program's rich history and the progress it has achieved over the years. I am confident that together, with your support and valuable feedback, we can continue to advance and evolve the program to new heights. I look forward to embarking on this journey with all of you and am excited about the contributions we can make to its continued success.

FAIR WINDS AND FOLLOWING SEAS



CDR Leedjia Svec

The DON HRPP team would like to wish CDR Leedjia Svec Fair Winds and Following Seas in her new assignment. We appreciate her vision, her tireless efforts to move DON HRPP forward, and her support for the Surgeon General of the Navy and everyone within the DON HRPP community. We also congratulate her on selection to Captain! Bravo Zulu!

SECNAVINST 3900.39E CH-1

There is an exciting opportunity for Navy commands to provide feedback on the current SECNAVINST 3900.39E CH-1, “Human Research Protection Program,” which includes the requirements for DON-conducted and supported research.

As a team, we understand the importance of collaboration in refining this instruction. Our collective efforts will ensure that we produce a polished and impactful instruction to guide Navy research efforts. By working together, we can leverage each person’s proficiencies and create a final document that reflects our unique skills and experiences.

DON HRPP sent an e-gram on 3 May 2024 requesting feedback and comments by 14 June 2024. The e-gram can be found on the DON HRPP milSuite group. We are committed to reviewing your feedback and will carefully consider every comment received. Regular updates will be provided on our progress.

As always, please reach out to your assigned point of contact with any questions. This is your opportunity to influence Navy research, and we look forward to hearing from you!

DON HRPP is Refreshing the Assist Visit Process!

The purpose of an assist visit is to provide support and expert guidance to enhance the effectiveness of the HRPP operations. It also allows us to work with you and your team to prepare for a future site assessment before the assurance renewal.

To achieve this purpose, we are thrilled to announce a renewed approach for these visits. Our primary goal is to streamline the process, making it more efficient and targeted towards the needs of the HRPP. By focusing our efforts on this goal, we aspire to maximize the impact of our hands-on assistance and training initiatives.

To help us better understand your current challenges and needs, we developed a questionnaire (*see image on right*) to gather specific information that will be used to create the agenda for the visit. The questionnaire will be emailed to the command in advance of the assist visit, or the compliance specialist will collect the responses verbally over the phone.

The questionnaire seeks the command's input to formulate focus areas for the visit including meeting with the command leadership, training, and topics for discussion. We want to work with you to assess current practices, identify any areas for improvement, and share best practices to empower your HRPP with the knowledge and tools needed for sustained success. Focusing on key areas, such as reviewing HRPP policies and procedures or developing a post-approval compliance monitoring program, will help further develop your HRPP goals.

At the culmination of our assist visit, we hope to leave you with actionable items that will pave the way towards a successful site assessment. The DON HRPP point of contact will continue to work with you following the visit and help address any questions.

We hope this renewed approach will make the process more efficient for all involved, and we look forward to our next assist visit with you!

Department of the Navy Human Research Protection Program (DON HRPP) Pre-Visit Questionnaire

The DON HRPP intends to conduct an assist visit at your command. To better prepare for and assist your command HRPP during the visit, please take a few minutes to review and answer the following questions then return the questionnaire to your DON HRPP point of contact (POC) by the date identified in the scheduling notice. Thank you.

1) Please provide the following information:

Name: [Redacted]

Role at the command HRPP: [Redacted]

Command name: [Redacted]

Contact information: [Redacted]

2) How many days is the command available for an onsite assist visit? [Redacted]

3) Would the Institutional Official (IO) like to meet with DON HRPP leadership?
 In-brief Out-brief Both Not at this time

4) Would you like us to conduct any training? Yes No

Topic(s): [Redacted]

5) What training method(s) do you prefer: *Check all that apply.*
 PPT Presentation Q&A Discussion Handouts
 Other: [Redacted]

6) Are there any concerns you would like for us to address or look into while on site?

7) Would you like for us to meet with a department or anyone specifically while on site?

8) Have there been any significant or notable changes within the command HRPP since our last visit?

9) Have you participated on an assist visit before? Yes No
 If yes, is there anything you would like to see done differently based on your past experience?

10) Is there anything DON HRPP can do for you before, or after, the visit?

NAMRU INDO PACIFIC Assist Visit

DON HRPP was delighted to visit the Naval Medical Research Unit (NAMRU) INDO PACIFIC in April 2024. We are grateful to the command for their generosity and their commitment to the protection of human subjects in the remarkable research initiatives in Southeast Asia. We look forward to seeing you all again in the near future!



Photo of NAMRU INDO PACIFIC and DON HRPP teams (left to right): CAPT John Brooks, Jonise Handy-Richards, Jazsmine Armstrong, Sophea Sout, Lay See (Joy) Tan, Nancy Dawood, and Derek Englis.